

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**IN RE: JOHNSON & JOHNSON TALCUM
POWDER PRODUCTS MARKETING,
SALES PRACTICES, AND PRODUCTS
LIABILITY LITIGATION**

**Civil Action No. 3:16-md-
2738-FLW-LHG**

MDL No. 2738

***THIS DOCUMENT RELATES TO ALL
CASES***

**THE PLAINTIFFS' STEERING COMMITTEE'S REPLY TO JOHNSON &
JOHNSON AND JOHNSON & JOHNSON CONSUMER INC.'S
MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS'
STEERING COMMITTEE'S MOTION TO EXCLUDE THE
GEOLOGICAL TESTING OPINIONS OF DRS. ANN G. WYLIE AND
MELINDA DARBY DYAR**

TABLE OF CONTENTS

TABLE OF CONTENTS	ii
TABLE OF AUTHORITIES	iii
I. INTRODUCTION.....	1
II. ARGUMENT	3
A. Ann G. Wylie, Ph.D.	3
1. Dr. Wylie is not qualified to opine on the validity of TEM testing and the findings of Drs. Longo & Rigler	3
2. Dr. Wylie’s opinions should be precluded because she failed to employ an appropriate methodology	5
B. Melinda Darby Dyar, Ph.D.	6
1. Dr. Dyar is not qualified to opine on the validity of TEM testing and the findings of Drs. Longo & Rigler	6
2. Dr. Dyar’s opinions should be excluded because they are based on unreliable methodology	9
III. CONCLUSION	14

TABLE OF AUTHORITIES

Cases

<i>Buzzerd v. Flagship Carwash of Port St. Lucie, Inc.</i> , 669 F. Supp. 2d 514, 522 (M.D. Pa. 2009).....	1
<i>Elcock v. Kmart Corp.</i> , 233 F.3d 734, 743 (3d Cir. 2000).....	1
<i>Fireman’s Fund Ins. Co. v. Videfreeze Corp.</i> , 540 F.2d 1171, 1180 (3d Cir. 1976)	2
<i>In re Unisys Sav. Plan Litig.</i> , 173 F.3d 145, 156-57 (3d Cir. 1999).....	1
<i>Lanzo v. Cyprus Amax Minerals</i> , no. MID-L-7385-16 AS (N.J. Super. Ct. Oct. 24, 2017).....	8

Other Authorities

Blount, AM. 1991. Amphibole Content of Cosmetic and Pharmaceutical Talcs. <i>Environmental Health Perspectives</i> . 94:225-230	8
Yamate et al., <i>Methodology for the Measurement of Airborne Asbestos by Electron Microscopy</i> 46 (1984).....	7, 10

I. INTRODUCTION

The Plaintiffs’ Steering Committee (“PSC”) respectfully submits this reply memorandum in support of its motion to exclude the opinions and testimony of Defendants Johnson & Johnson and Johnson & Johnson Consumer, Inc.’s (together, “J&J”) asbestos testing experts, Ann G. Wylie, Ph.D. and Melinda Darby Dyar, Ph.D.¹

As outlined in the PSC’s Brief and the reply below, neither Dr. Wylie nor Dr. Dyar are qualified to opine on the testing done by Drs. Longo and Rigler. While the Third Circuit has adopted a “liberal standard” for qualifying experts, the court still must focus on whether the qualifications (training, expertise, and experience) that an expert does have provide a foundation for the witness to testify meaningfully on a given matter.² A basic understanding of a general subject matter does not alone qualify a witness as an expert on that specific subject.³ Even when a witness is

¹ *The Plaintiffs’ Steering Committee’s Memorandum of Law in Support of its Motion to Exclude the Geology Testing Opinions of Drs. Ann G. Wylie and Melinda Darby Dyar*, Dkt. 9741-1, is referred to herein as “PSC Brief.”

² See *Elcock v. Kmart Corp.*, 233 F.3d 734, 743 (3d Cir. 2000); see also *Buzzerd v. Flagship Carwash of Port St. Lucie, Inc.*, 669 F. Supp. 2d 514, 522 (M.D. Pa. 2009) (citing *Rose v. Truck Centers, Inc.*, 611 F. Supp. 2d 745, 749 (N.D. Ohio 2009) (“The issue with regard to expert testimony is not the qualifications of a witness in the abstract, but whether those qualifications provide a foundation for a witness to answer a specific question.”)).

³ See *In re Unisys Sav. Plan Litig.*, 173 F.3d 145, 156-57 (3d Cir. 1999).

qualified as an expert in a particular field, the court cannot permit the witness to testify as to matters that are outside her area of expertise.⁴

The expert opinions of Drs. Wylie and Dyar far exceed their areas of expertise. The PSC does not dispute that Drs. Wylie and Dyar have strong laboratory backgrounds, but neither Dr. Wylie nor Dr. Dyar have expertise or experience in using transmission electron microscopy (TEM) to identify asbestos in a bulk or air sample. To illustrate the PSC's argument: an orthopedic surgeon may have expertise in reviewing an X-ray or CT scan for purposes of treating a broken bone but have no expertise in using an X-ray or CT scan for purposes of diagnosing lung disease. That is essentially what J&J is doing with Drs. Wylie and Dyar. Instead of retaining experts with expertise and experience in identifying asbestos using TEM to review Drs. Longo and Rigler's work, they retained experts with zero expertise and experience. Because Drs. Wylie and Dyar lack the necessary qualifications, experience and expertise, they should be precluded from commenting on TEM testing or critiquing the TEM testing of historical samples conducted by Drs. Longo and Rigler.

⁴ See *Fireman's Fund Ins. Co. v. Videofreeze Corp.*, 540 F.2d 1171, 1180 (3d Cir. 1976).

Further, for the reasons outlined below and in the PSC's motion, both Dr. Wylie and Dr. Dyar's methodology in reaching their opinions falls well short of the *Daubert* standard.

II. **ARGUMENT**

A. **Ann G. Wylie, Ph.D.**

1. **Dr. Wylie is not qualified to opine on the validity of TEM testing and the findings of Drs. Longo & Rigler**

J&J claims that Dr. Wylie has devoted her career to the laboratory, not the courtroom, as though that mere fact is sufficient for her opinions to be admissible in this case. But the truth is that she has a long history of working for the talc industry.⁵

The representations made concerning Dr. Wylie's consulting and litigation history with J&J are equally misleading. Although Dr. Wylie claimed in her deposition she began working for J&J in late 2018, it was actually in 2017.⁶ This is critical as both Dr. Wylie and J&J failed to disclose Wylie's affiliation with J&J when she testified before the FDA Talc symposium in November 2018. At that time,

⁵ She consulted for Avon Products, R.T. Vanderbilt Company and Desert Mineral Products, all talc companies, in the 1970's and 1980's. *See* Wylie Deposition, 20:17-22:9; 30:1-9. She gave three or four depositions in talc litigation between 1980 and 1990 for a talc manufacturer and appeared in a lobbying video for R.T. Vanderbilt Co., a talc supplier. *See* Wylie Errata, **Exhibit 1**. She has also consulted for and received research grants from multiple asbestos companies. *See* Wylie Deposition, 22:9-26:25; 30:10-31:9.

⁶ *See* Wylie Errata.

Dr. Wylie had already been hired by J&J.⁷ And while J&J claims that the FDA turned to Dr. Wylie for her expertise, in reality, J&J provided her name to the FDA and facilitated her invitation to the symposium.⁸ During the symposium, she criticized Dr. Longo's TEM results finding asbestos in Johnson's Baby Powder without disclosing her conflicts or informing the FDA that she, in fact, had no expertise in TEM methodology.⁹ As the meeting was closed to the public,¹⁰ there was no one who knew the truth about Dr. Wylie's lack of expertise and bias to challenge her unsupported and unqualified assertions.

Although Dr. Wylie held herself out to the FDA as an expert in TEM, she was forced to admit in her deposition that she has *never* "used TEM to test for the presence of asbestos."¹¹ Given that testimony, it is impossible for her to be qualified as an "expert" in the use of TEM to test for the presence of asbestos.

While the PSC moves to exclude Dr. Wylie's opinions concerning TEM because she is clearly not qualified to offer such evidence, the PSC is not moving to

⁷ Wylie Errata. J&J did not disclose that Dr. Wylie was a consultant to the FDA. See JNJTALC000880470, attached hereto as **Exhibit 2**.

⁸ See JNJTALC000880470.

⁹ See JIFSAN Main Session (Nov. 28, 2018) at 145:15-146:6 (criticizing data from testing of Johnson's Baby Powder), attached hereto as **Exhibit 3**.

¹⁰ See *Defendants' Memorandum in Opposition to Plaintiffs' Motion to Exclude the Geological Testing Opinions of Drs. Ann G. Wylie and Melinda Darby Dyar* ("Def. Opp.") at 16.

¹¹ Wylie Dep. 227:12-16.

exclude Dr. Wylie's opinions related to polarized light microscopy (PLM). To be clear, the PSC disagrees with these opinions, but she has the necessary qualifications to opine on PLM techniques.

2. Dr. Wylie's opinions should be precluded because she failed to employ an appropriate methodology

Dr. Wylie's methodology is also at issue. Dr. Wylie has set forth her own requirements to determine whether a particle of microscopic size meets the size, shape, chemical and crystalline structure of asbestos. Dr. Wylie's definition of asbestos is not consistent with the requirements established by either the EPA or NIOSH.¹² Moreover, Dr. Wylie's requirement of an indeterminate population of asbestiform particles does not follow sound methodology as it is untestable and therefore not reproducible.¹³

Dr. Wylie's opinion's concerning the presence of asbestos in the mines that were used to source J&J's Talcum Powder Products should also be precluded as based upon unreliable methodology. In this regard, Dr. Wylie acknowledged that she was not shown and did not consider critical information. In reaching her conclusions, Dr. Wylie did not conduct a thorough review of publicly available information but relied on upon only limited public information and published literature regarding the

¹² *Id.* at 109:8-20; 140:18-141:10.

¹³ *Id.* at 246:20-247:2.

Vermont and Italian mines. More importantly, in rendering her shallowly supported net opinion, Dr. Wylie failed to consider J&J's internal testing documents demonstrating the presence of asbestos in the Vermont and Italian mines. As a result, her ultimate opinion that the Vermont and Italian mines are free from asbestos is based on a flawed understanding of the geology and mineralogy of those mines. When confronted with numerous documents during her deposition that she had not seen, Dr. Wylie conceded that they were relevant to the questions she was asked to examine.¹⁴ This pertinent information was within J&J's custody and control. While it may have been a strategic decision on the part of J&J not to provide this information to her, Dr. Wylie's failure to consider this evidence makes clear that her opinions are unreliable and therefore, inadmissible.

B. Melinda Darby Dyar, Ph.D.

1. Dr. Dyar_is not qualified to opine on the validity of TEM testing and the findings of Drs. Longo & Rigler

J&J continually touts Dr. Dyar's experiences working with NASA. While this is certainly prestigious, it is not relevant to the current litigation. Dr. Dyar may be qualified to use an electron microscope when analyzing materials in an unconstrained environment (like the moon) but analyzing material for the presence of asbestos fibers in a specific sample from a specific mine is a much different

¹⁴ Wylie Dep. at 273:16-274:23.

inquiry, requiring specialized expertise. This inquiry should be addressed by employing generally accepted standards like those created by the International Organization for Standardization (ISO) and Environmental Protection Agency (EPA), standards Drs. Longo and Rigler have been applying for decades. In contrast, Dr. Dyar had not reviewed these standards until she was hired by J&J.¹⁵ In fact, she has no background in identifying asbestos in a specimen when she does not already know it is present.¹⁶ That is the expertise that is relevant here. Asbestos is unique and poses unique microscopy challenges, which is why such testing protocols like Yamate 1984,¹⁷ the EPA regulations on asbestos in schools,¹⁸ and ISO 22262-1.¹⁹ and ISO 22262-2.²⁰ exist. If specialized expertise was not required, then there would

¹⁵ Dyar Dep. at 62:22-63:14; 63:18-21; 67:5-12; 67:16-68:22.

¹⁶ While Dr. Dyar may have looked at asbestos fibers under the microscope, she has always known what she was looking at ahead of time, and never tested to determine if it contained asbestos. *See* Dyar Dep. 50:1-4; 58:10-17; 297:7-19.

¹⁷ Yamate et al., *Methodology for the Measurement of Airborne Asbestos by Electron Microscopy* 46 (1984) (“Yamate 1984”) **Exhibit 4**.

¹⁸ *See* EPA Regulations (AHERA), 40 C.F.R. Pt. 763, Subpt. E, App. A, at 871, 891, 893 (validating visual analysis of bundles and fibers, and making clear that quantitative data is not required for either EDXA (or SAED for that matter)), attached hereto at **Exhibit 5**.

¹⁹ *See* ISO 22262-1, Sampling and Qualitative Determination of Asbestos in Commercial Bulk Materials (2012) (Exhibit 97, PSC’s Asbestos Opp.).

²⁰ *See* ISO 22262-2, “Air Quality – Bulk materials – Part 2: Quantitative determination of asbestos by gravimetric and microscopical methods” (2014), attached hereto as **Exhibit 6**.

be no need for such exacting standards and methods focused on how to determine whether asbestos is present in a bulk or air sample.

J&J incorrectly claimed that Dr. Longo first learned the ISO protocols for this litigation. That is simply not true. The email J&J cited in support of this unfounded assertion in no way indicates this, and instead, discusses ISO2226-2 in comparison to their internal protocol.²¹ The only thing that was new for Dr. Longo when analyzing talcum powder samples was the Blount preparation method, a concentration method for talcum powder testing that is peer-reviewed and published.²² As Dr. Longo has explained, Dr. Blount's concentration method of "separating out the denser amphiboles versus the talc material" enables "a more sensitive analysis."²³ Dr. Longo was familiar with ISO protocols regarding the identification of asbestos particles and had used those protocols for years.

J&J claims that Dr. Dyar has published relevant papers on asbestiform minerals.²⁴ Dr. Dyar's testimony contradicts J&J's argument as she conceded that

²¹ See Exhibit 34, Def. Opp. (Dkt. 9867-34).

²² See Dep. Of William E. Longo, Ph.D. (Feb. 5, 2019) at 291:12-24 (Exhibit 70, PSC Asbestos Opp.); *Lanzo v. Cyprus Amax Minerals*, no. MID-L-7385-16 AS (N.J. Super. Ct. Oct. 24, 2017) (Exhibit E33, Def. Opp. (Dkt. 9867-28); *see also* Blount, AM. 1991. Amphibole Content of Cosmetic and Pharmaceutical Talcs. *Environmental Health Perspectives*. 94:225-230 (Exhibit J, PSC Brief (Dkt.9741-5)).

²³ Longo Dep. at 289:22-290:7.

²⁴ Def. Opp. at 9 and fn. 29.

she has never published a peer-reviewed article regarding how to determine if there is asbestos in a product,²⁵ nor has she published on how to use EDS, SAED, or PLM to identify asbestos in materials.²⁶ J&J also cites to multiple other papers authored by Dr. Dyar.²⁷ However, this attempt to bolster Dr. Darby's qualifications is unavailing because her contributions to the papers relate to the evaluation of iron and the iron redox ratio, topics unrelated to the identification of asbestos.²⁸

2. Dr. Dyar's opinions should be excluded because they are based on unreliable methodology

Dr. Dyar's lack of experience and expertise with generally accepted asbestos testing methods is obvious when you consider her claims regarding EDXA data. Dr. Dyar is critical of Drs. Longo and Rigler for using the "eyeball" method of estimating EDS results, asserting that it is unsupported by the scientific community and is a flaw in their methodology.²⁹ The flaw, however, is in Dr. Dyar's methodology. Dr. Dyar cites ISO 13794 for the requirement that there be *quantitative* EDXA data. ISO 13794 does not require quantitative data, but

²⁵ Dyar Dep. at 46:24 – 47:2.

²⁶ *Id.* at 47:3-19.

²⁷ Dyar Report at 5 and fn.5.

²⁸ Dyar Dep. at 58:18 – 60:16.

²⁹ Dyar Report at 19; *see* Def. Opp. at 36-38.

specifically mentions that the EDXA spectrum may be either *qualitative* or *quantitative*.³⁰

E.2.3 EDXA measurements

Interpretation of the EDXA spectrum may be either qualitative or quantitative. For qualitative interpretation of a

She also cites Yamate 1984 which again, contradicts her claim that quantitative data³¹ is required.

worse. In view of these ambiguities, and due to inherent practical difficulties in obtaining representative quantitative EDS elemental analyses from submicroscopic fibers, the present Level II and Level III protocols specify the use of only qualitative EDS spectra, which are often very valuable for screening purposes in the identification procedure. For example, in distinguishing between tremolite and actinolite type of amphibole, actinolite usually contains Fe. but tremolite does not.

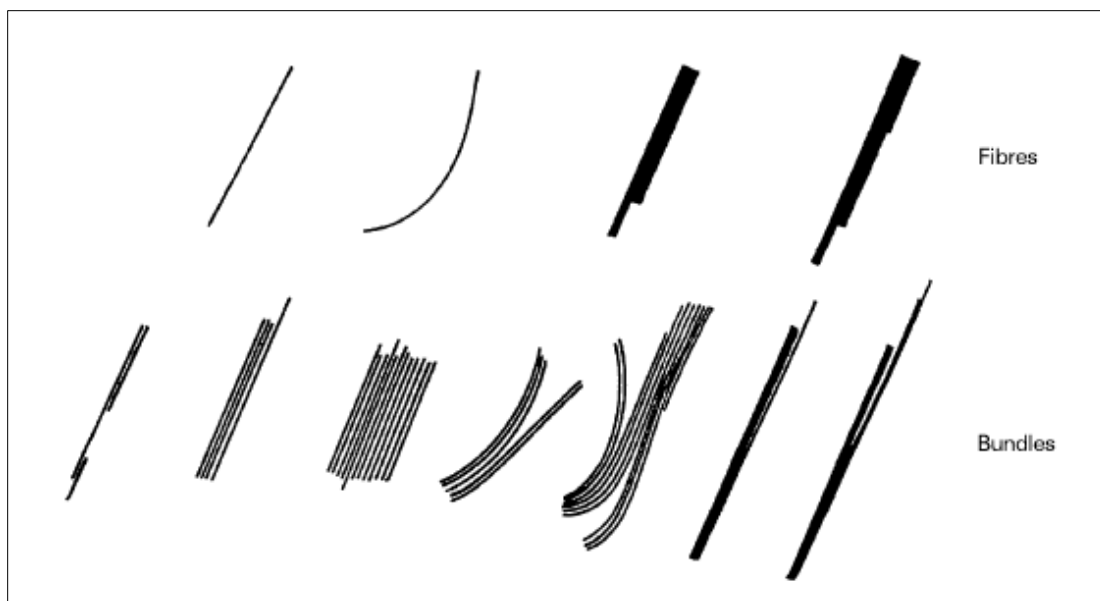
Similarly, her criticism of the “eyeball” approach to identifying a fiber or a bundle³² is also belied by ISO 13794.³³ This protocol has pictures of “fibers” and “bundles” (excerpted below) which instruct the analyst to look at the structures he/she is seeing in the microscope and describe them. This is the same method for describing “fibers” and “bundles” Drs. Longo and Rigler employed in reaching their opinions and preparing their report.

³⁰ See ISO 13794, “Ambient Air – Determination of asbestos fibres – Indirect-transmission electron microscopy method,” at 45 (1999), attached here to as **Exhibit 7**.

³¹ Yamate 1984 at 49.

³² Def. Opp. at 36-38.

³³ ISO 13794, at 37.



It was entirely proper for Drs. Longo and Rigler to use and follow the published and generally accepted standards on how to determine if there is asbestos in a bulk sample generally (e.g., ISO 22262-1 and the EPA documents), and in talcum powder specifically (e.g., ISO 22262-2 and the Blount 1991 paper). Dr. Dyar's criticisms are incorrect and unsupported by generally accepted standards. In addition to being a methodological flaw in reaching her opinions, this misapplication of the controlling standards also illustrates her lack of expertise and experience in real world testing materials for the presence of asbestos.

Dr. Dyar also criticizes Drs. Longo and Rigler for not properly training their personnel for possible impurities in talc samples where "the possible mineralogy is unconstrained." Dr. Dyar's methodology relies on speculation. She claims that the analysts cannot "understand or interpret their results, especially where, as here, the

impurities are tiny, and many possible minerals can be present.”³⁴ Dr. Dyar acknowledges that she cannot say what the minerology is in talc mines or what possible minerals could actually be present.³⁵ Her report outlines minerals similar to talc in chemical formula but she cannot say that any of these minerals could feasibly be found in the historical samples provided by Johnson & Johnson or Imerys.³⁶ She claims there are hundreds of possibilities for misidentification, but is unable to opine that any of the minerals subject to misidentification may actually be found in Vermont, China or Italy where J&J sourced its talcum powder products.³⁷

J&J responds to this *Daubert* challenge by claiming that since Dr. Dyar is not offering any opinions related to the mines themselves, that anything to do with the minerals contained in the mine is moot.³⁸ This argument is illogical and groundless. The minerals found in the mine ore necessarily limits what can be in the final product. By claiming that thousands of minerals could be in the ores from the mines without knowing anything about the geology and mineralogy of the mines themselves, her opinions are not based in sound science, but mere conjecture. This is especially true when information regarding the constrained environment is

³⁴ Dyar Report at 4.

³⁵ Dyar Dep. at 163:18-164:16.

³⁶ Dyar Report at 9.

³⁷ Dyar Dep. 163:18-164:16.

³⁸ Def. Opp. at 33-35.

available and could have been reviewed.³⁹ She, like Dr. Wylie, failed to consider the scientific literature, other public information, and J&J and Imerys's internal documents that demonstrate that asbestos is commonly found in talc ore generally, and is specifically documented in the mines that were used to source J&J's Talcum Powder Products. Dr. Dyar analyzed Drs. Longo and Rigler's work as if they were analyzing a sample from the surface of the moon when, in fact, there is a multitude of data that demonstrates that talc mines are not an "unconstrained environment." Rather, they are "constrained" environments that contain known and very well described subsets of minerals.

In an attempt to justify this incurable flaw in Dr. Dyar's methodology, J&J states that Drs. Longo and Rigler did not purport to consider the minerals present in the talc mines either.⁴⁰ This is simply ***not true***. Drs. Longo and Rigler relied on and referenced numerous J&J testing documents which demonstrated the presence of asbestos in the mines and scientific articles on the geology of the mines.⁴¹ Dr. Dyar's

³⁹ For example, her report claims that some of the minerals identified by Drs. Longo and Rigler in the historical samples could be rondorfite. *See* Dyar Report at 18 fn. 34. However, rondorfite is only present in Russia, South Ossetia, Germany and the Czech Republic. *See* "Rondorfite_Mineral information, data and localities," www.Mindat.org (last accessed June 15, 2019), attached hereto as **Exhibit 8**. J&J did not source its talcum powder from any of these countries.

⁴⁰ Def. Opp. at 35.

⁴¹ Longo & Rigler Supp. MDL Rep. at 30 (Exhibit 67, PSC Asbestos Opp. (Dkt. 9902)).

statements in this regard amount to nothing more than speculation and should be excluded.

III. CONCLUSION

A *Daubert* inquiry boils down to whether the expert is qualified, whether when answering a scientific question, she follows the standards and protocols in the courtroom that truly qualified experts adhere to in the real world, and whether the opinions “fit” the case. In the real world, J&J knew as far back as 1973 that “Transmission Electron Microscopy is the only absolute proof with electron diffraction for the identification of asbestos in talc.”⁴² Over the intervening decades, very detailed procedures for using TEM to look for asbestos in materials in various kinds of materials have been published as EPA and ISO standards became generally accepted by scientists in the field. Dr. Longo and Rigler have followed these procedures when utilizing TEM to analyze historical talcum powder samples for the presence of asbestos. In sharp contrast, Dr. Wylie and Dr. Dyar have *never* used TEM to analyze a sample for the purpose of detecting asbestos. They lack the requisite qualifications, expertise and experience to offer opinions related to the use of TEM and the TEM testing of historical samples conducted by Dr. Longo and Rigler. Finally, their opinions regarding the geology of the mines used to source

⁴² See JNJMX68_000017515 (Exhibit 41, PSC Asbestos Opp.).

J&J's Talcum Powder Products are the product of flawed and unreliable methodology.

For these and the reasons outlined more fully in the PSC's Brief, the Court should exclude the opinions and testimony of Ann Wylie, Ph.D. related to the geology of the mines used to source J&J's Talcum Powder Products, the presence of asbestos in the source mines and the Talcum Powder Products, the definition of asbestos, the use of TEM testing generally, and the TEM testing of historical samples conducted by Drs. Longo and Rigler. In addition, the Court should exclude the opinions and testimony of Melinda Darby Dyer, Ph.D. in their entirety.

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Respectfully submitted,

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